IRIS Medical®
OcuLight® SL / SLx
Service Manual

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PLEASE NOTE: This Service Manual is intended to be a general guide for the OcuLight® infrared family, but because of different versions of electronics within the same model number, it may not be an exact representation of your product. Contact Technical Service if you have any questions.

1.0 INSTALLATION

1.1 Location

The OcuLight has been designed to be stacked on existing operating room equipment such as vitrectomy devices. Choose a well ventilated location; operating room and office environments are suitable. The recommended operating room temperature should be between 50 and 90 degrees Fahrenheit (10 and 32 degrees Celsius) and the relative humidity between 20 and 80 percent.
Do not place the OcuLight near open flames.

1.2 Electrical Connection

A. North American Installation

The OcuLight is equipped with a hospital grade (green dot) three-wire grounding plug. This plug fits only a grounding-type AC receptacle. This is an essential safety feature.

B. Installation in Other Locations

A power cord appropriate to your area is provided. Replacement cords can be obtained locally to match the IEC320 standard appliance inlet on the back panel. Always use a three-wire grounding cord set. Do not alter the appliance inlet, as it contains protective fusing. Follow local electrical codes for installation to ensure proper grounding (earth connection).

****Note:** Do not defeat the purpose of the grounding pin. This equipment is intended to be electrically grounded. Contact a licensed electrician if your outlet prevents you from inserting the plug.

2.0 OCULIGHT SL/SLx SYSTEM

2.1 System Overview

A. Power Supply

Power is supplied from the line through an IEC motor base connector with integral fusing for both sides of the line voltage. Power is routed via an internal fuse to the key switch and then to a transformer (T1), which supplies low voltage power at approximately 24 VDC. The voltage is then re-regulated and distributed to the internal loads. When power is applied by turning on the key switch, the processor performs a series of diagnostic checks. When the diagnostic checks are completed and the remote interlock is closed, the microprocessor illuminates the front panel displays, and after a three second delay, goes into the standby state.

If the remote interlock is open, the FootSwitch and laser power system will be inoperable and the message: "No Remote Interlock" will be displayed. When the remote interlock is closed, the system will return to a standby state with the power set to zero. To begin treatment/laser emission, the operator must set a power level, press the Treat button (which will switch on the aiming laser), and then depress the FootSwitch.

B. Controls

The OcuLight's front panel controls consist of the key switch (wired into the power circuit and explained above), controls, and indicators linked to the microprocessor control system. The microprocessor reads the controls, reports back to the operator through the displays, and sets up the control sequences within the unit.

Front panel treatment controls are TREAT/STANDBY, POWER LEVEL, Pulse DURATION, REPEAT INTERVAL, AIMING BEAM intensity, TONE VOLUME level, LIO illumination intensity and COUNTER RESET.

The requested power is adjusted via a rotary optical encoder, which counts up or down from a starting point. At each initial start sequence involving the resetting of the key switch, the power level is reset to zero. The power will also be reset to zero every time a delivery device is connected to the front fiber port. The power control is read by the control system when the system is energized in STANDBY or TREAT mode, but not when the laser diode is active (FootSwitch DOWN in TREAT mode). The front panel POWER LEVEL indicator is driven by the processor from the same data used by the system to control the power delivered.

The Pulse DURATION and REPEAT INTERVAL controls are mechanical encoder switches, which are read and interpreted by the microprocessor. They can be physically actuated in any mode of the unit. The signals are read at regular intervals and used to update the displays and the timing values. They are not read or updated while the FootSwitch is activated. As with the power control, the displayed value is the value used to deliver the laser pulse train.

✓Note: More information on the controls can be found in the IRIDEX OcuLight Diode Laser System Operator Manual.

C. FootSwitch Circuit

A FootSwitch controls laser emission. The FootSwitch cable contains four wires: +5 V supply, FootSwitch return 1, FootSwitch return 2, and ground. In order to initiate a laser emission, the double-pole, double-throw switch must disconnect the two return lines from ground and connect the +5 V supply. Four wiring faults must occur to initiate a false response. When entering TREAT mode, the processor checks the integrity of the FootSwitch connection. If the FootSwitch is disconnected or the shorting safety circuits are open, the message: "Connect FootSwitch" is displayed.

✓Note: TREAT mode cannot be entered until a properly connected FootSwitch is detected.

To initiate laser action, the FootSwitch return lines individually provide power to the two laser control relays and provide a logical line through an AND gate IC to the microprocessor. Laser duration is controlled by the microprocessor through the control amplifiers and transistors. The relays provide a backup system to assure that laser emission cannot occur when the FootSwitch is not activated.

✓Note: Laser optical power and laser currents are monitored to detect control system failure.

D. Optical System

The IRIDEX OcuLight infrared optical system consists of one or two treatment laser diodes, depending upon the model, with a wavelength approximately at 810 nm and capable of an output power of up to 3 Watts. The aiming beam (pilot) laser is capable of 2.5 mW output and is approximately 650-670 nm in wavelength. The treatment laser beams are combined and fed through a beam sampling optic, which transmits >95% of the beam and diverts <5% to a scattering attenuator and a pair of power monitoring photodiodes. The beam is then optically combined with the aiming (pilot) laser beam and focused into the delivery device fiber.

✓ Note: A lack of aiming beam in the Standby mode or with the beam intensity control knob fully turned counter-clockwise may not be a malfunction.

Failure or degradation of power in either treatment laser will allow continued operation at limited power levels. The low power response is described in the Operator Manual and in the software description. If the limited power mode is observed, factory repair should be scheduled at the earliest convenient time; however, in the interim, treatment may be safely continued.

The laser system is designed with many redundant electronic safety features to prevent and inadvertent laser emission. A variety of safety checks ensure that the unit is operating as intended.

The infrared laser diodes incorporated in the product are extremely stable and are electronically pulsed to provide the requested pulse durations. There is no need to run the lasers continually in order to stabilize output power or ensure regulation. Separate FootSwitch signals and a gate from the microprocessor must activate both relays.

✓Note: Treatment laser diodes are always completely de-energized and shorted with a shunting relay until power is requested by a FootSwitch activation while in TREAT mode

The laser power control method relies on light loop regulation with maximum current limits (hardware/software) set as a back up. To match the requested power level, photodiodes are used to measure and monitor the optical beam and then control the amount of current to the diode(s). This is called the light-loop feedback circuit.

A laser power level command is generated by the processor through a digital-to-analog converter and sent to the power control amplifier. This signal is balanced against the laser power signal from the current sense amplifier. The microprocessor reads the signal from two independent photodiodes and adjusts the current drive to produce a calibrated output. The final output depends on agreement (within error limits) between the two photodiodes and a preset calibration curve for light output as a function of current. Discrepancies will cause call service messages to appear (refer to Appendix B for a list of "Call Service" messages) and laser shutdown. Time from detection of discrepancy to laser shutdown does not exceed 20 msec.; time from detection of discrepancy to detect errors in current drive is approximately 1 msec., time to detect light errors is 20 msec.

If the two-photocell readings do not match between each other and the requested power, within 10% of full scale, the system deactivates the lasers and indicates a fault. The A-D converter monitors both laser currents to assure that no power is delivered in non-emission modes and to assure correct output.

A separate visible aiming laser diode circuit is included in the system. The aiming diode also uses light regulation based on an integral sensing photodiode. The control amplifier is fed from a front panel potentiometer by way of the microprocessor.

E. External Connections and Controls

The fiber port includes a proprietary electrical connection (U.S. Patent 5,085,492) that verifies the presence of an IRIDEX fiber and provides the processor with data regarding the type of delivery device connected and its calibration lookup table. The identity is determined by reading an embedded resistance, of which there are eighteen potentially valid values separated by invalid bands. This simple circuit is capable of detecting and rejecting short circuits, open circuits as faults or attempts to bypass this safety function.

The OcuLight SL/SLx systems have a front panel connection labeled "SmartKey®". The SmartKey provides electrical connection between the laser console and a delivery device or accessory.

The SmartKey connection provides feedback of spot size selected when using the slit lamp adapter. This feedback is used to adjust the display to correspond to the transmission efficiency associated with each spot size. Laser emission is inhibited if the spot size control is not properly detected before actuating the FootSwitch.

In older models, a shunted SmartKey was required for EndoProbe® use. The shunted SmartKey is provided as a means of disabling the laser when the safety filter was removed from the operating microscope. In later model laser systems, a message prompts the operator to verify that adequate safety filters are installed prior to proceeding.

F. Timing

The timing system used to control pulse delivery uses a counter to divide the system crystal clock time into smaller time ticks. These ticks are read by the microprocessor and are counted up to the desired interval. The clock counter is free running so that no latency of response accumulates in the timing from other software processes. The time ticks are also used to stimulate the processor to reset the "watchdog" chip. If the clock or the timer fails, the watchdog will independently time out and take over control of the laser power relays through the reset lines. If the watchdog time-out occurs, the system shuts down and the laser power is disabled.

G. Software

The software performs the functions of system verification, control interpretation, display control, and treatment laser control. The software conforms to the state diagram and the state descriptions. Software verification was performed during development and is performed at all revisions to assure function according to the software state descriptions. The software verifies the battery-backed RAM data for integrity at power up against an included check sum.

Software is written in C and compiled by the Archimedes C Compiler Version 2.21 a (80196) running on an IBM AT compatible PC. The compiled object code is approximately 45 KB in size and source code is archived at every revision. A complete copy capable of reproducing each version of shipped code is held in the archives. The software revision number can be read on the display when the product is in diagnostic mode. Software versions are recorded in the device history and updates are recorded as they occur.

H. Hazard Prevention

To prevent hazards, the following redundant safety systems are built into the OcuLight unit:

1) Dual power monitors
2) A-D reading backs the D-A values
3) Hardware/software tracking current limits
4) Electro-mechanical relays to backup the control transistors
5) Redundant contacts/lines to the FootSwitch
6) Redundant power control relays in the laser circuit
7) Watchdog chip to verify clock action.

I. Beam Attenuator

The treatment and aiming lasers are turned on and off by software and hardware controls. The lasers are not energized in modes not requiring laser emission. There are two relays in the treatment laser power circuit that prevent emission when the interlock or FootSwitch is open. The aiming beam is a separate diode laser; therefore, the Treat/Standby switch provides virtually instantaneous on/off control of laser emission. For this reason, the Treat/Standby switch was approved as an alternate means of accomplishing the Aiming Beam Attenuator Requirement of 21 CFR 1040.10(f)(6)(ii). (Refer to 9010164-02)

J. Line Voltage Selection

The line voltage selection is made within the IEC power connector. To change voltage selection, remove the power cord, release the latch (use tweezers or a small screwdriver to accomplish this), and remove the fuse holder above the main inlet. Remove and rotate the voltage selection jumper. Replace the jumper devices so that the selected voltage faces outward. Replace the fuse drawer and the cord. Install the correct fuses according to the fuse label on the rear panel. The standard IEC mains input connector allows attachment of any mains cord appropriate to the locality of use. USA and Australia require a specific hospital-grade cord and plug set. For other locations, use a cord approved by BSI, UL, TUV, or other safety-testing agency recognized by local authorities

The remote interlock connector (located on the back panel) provides continuity to the power relay control circuit. This is a very low voltage secondary control circuit (~ 6 VDC). Any combination of normally closed switches may be wired in series through the two pins of the interlock connector. Some jurisdictions require that an emergency off switch be available at a convenient location away from the laser console; other jurisdictions require that a remote interlock be installed on the doors of the operating room.

A skilled electrician or plant engineer will be able to add interlock functions by fixing a ring of switches to the remote interlock connector. The connector is REDEL PAG-MO2-GLAC39G, manufactured by Lemo SA of Switzerland. If additional plugs are required, they may be purchased locally or by contacting the IRIDEX service department.

K. "Call Service" Description (Error Codes)

When the OcuLight detects an internal failure, it will shut off the laser, disable all controls, and the message: "Call Service" will be illuminated along with an error code number indicating which failure was detected. To verify that an uncorrectable problem has occurred, switch the key off and back on. If the failure is still displayed, turn the unit off and contact the IRIDEX service department. A list of error codes and corresponding descriptions appear in Appendix B.

L. "Low Power Actual" Mode

If the system cannot deliver the level of requested power, the laser will shut off with a "Low Power Actual" reading and the actual power level available will flash on the display. The power output will automatically be adjusted to the maximum level of power that can be achieved without triggering another fault. This may allow the finishing of a procedure before returning the unit for service.

2.2 SYSTEM OPERATION AND DIAGNOSTICS

A. OVERVIEW OF DIAGNOSTIC MODE

The OcuLight has several modes of operation. Diagnostic mode is used to measure internal electronic values in the system, record various fault conditions, deliver laser pulses without regard to some minor of faults, and to monitor the cumulative pulse counts. Diagnostic mode should not be accessed by the user unless there is specific instruction to do so.

In Diagnostic mode, the power level knob and pulse duration knob still control the unit in the same way as in other modes; however, the repeat interval knob and counter reset button are now used to step through and select different diagnostic functions.

When delivering pulses, the system will use the current settings of the power, pulse duration, and repeat interval knobs. In diagnostics, it is only possible to monitor the pulse duration and repeat interval values while in function #0.

Warning! In diagnostic mode, many of the safety checks are disabled; it is therefore possible to operate the laser outside of the normal limits. Diagnostic mode should never be used while treating a patient unless instructed by an authorized IRIDEX Service Technician.

Display Format:

Due to the limited amount of information that can be displayed on the front panel at any one time, diagnostic information is displayed in stages. In a normal user mode such as Standby, the display has the following format:

POWER	PULSE LENGTH	PULSE INTYERVAL	COUNTER

In Diagnostic mode, most of the information is displayed in this format:

POWER	VALUE 1	VALUE 2	FUNCTION

For example, Diagnostic menu #1 (indicated by the "1" in the COUNTER display) displays the electrical current through the laser diode(s). For this function, a typical display would appear as follows:

1000	1.52	1.48	1

This example above shows that in diagnostics menu #1, the set power level is 1000 mW, diode #1 has a current reading of 1.52 A and diode #2 (if present) has a current reading of 1.48 A.

POWER	HIGH DIGITS	LOW DIGITS	7

In Diagnostic Menu 7, pressing and holding the Standby/Treat button can display the total number of pulses on the laser system. The Duration and Interval displays show the total number of pulses on the system. Because the number of pulses could be larger than four digits (> 9999), it is split between the two displays. In the example below, 100,843 pulses were delivered.

	10	0843	7

Diagnostic Functions

The following table lists the function numbers and their associated measurements as displayed on the front panel.

Power	Duration Display	Interval Display	Counter (Menu #)
	Pulse duration	Repeat interval	0
	Diode current A	Diode current 2	1
	Milliwatts at P.C.A.	Milliwatts at P.C.B.	2
	Watch Dog	RC Count	3
	Error Buffer	Error Index	4
	Probe KΩ	Fiber index selected	5
	+5 V reading	+12 V reading	6
Firmware version displayed (Press Standby/Treat button to display Pulse Count)			7
Selection of SmartKey requirements			8
Error Log Retrieval			10

B. USING DIAGNOSTICS

Entering Diagnostics

To enter diagnostics, place the unit into Treat mode. (Note: In some versions, a delivery device must be connected in order to enter this mode.) Push and hold the Treat/Standby button and then push and hold the Counter Reset button until the unit beeps and both the Treat and Standby lights are illuminated. Remove your fingers from both buttons. Both the Treat and Standby lights should still be lit.

Diagnostic Menus

The menu number is displayed in the counter window. To toggle between menus, press the counter reset button. The menu description will be displayed in the Alphanumeric window while the values will be displayed in the duration and repeat interval windows. The following diagnostic information is available in the eight menus:

Menu #1: Current required power for the device that is currently connected. Current A appears in the DURATION window; current B appears in the REPEAT INTERVAL window.

✓Note: These values can be checked to evaluate the aging of the Diode Laser(s).

Menu #2: Milliwatts of power as indicated by the photocell in the optic box. Photocell #1 appears in the DURATION window; photocell #2 appears in the REPEAT INTERVAL window.

✓Note: These values should be within 10% of the requested power.

Menu #3: Indicates watchdog and RC count. The watchdog value appears in the DURATION window (values should be between 64 – 130); RC count appears in the REPEAT INTERVAL window (values should be between 235 – 270).

Menu #4: Indicates the error buffer and error index. The error buffer appears in the DURATION window and indicates which error has occurred; the error index appears in the INTERVAL window and indicates the sequence that the error has occurred. A "0" in the Interval window indicates the most recent error and by rotating the INTERVAL knob, the next seven errors are recorded. A "0" in the DURATION window indicates that there has never been an error reading.

✓Note: The unit can store a maximum of 8 error codes (0 through 7) in the error Index, with the most recent error being assigned to 0.

Menu #5: Indicates the resistance and the delivery device index of the delivery device currently connected to the OcuLight. The resistance appears in the DURATION window; the index appears in the REPEAT INTERVAL window. The following table lists the devices and their corresponding resistance and index:

Device	Resistance (Ohms)			Device Index
	High	Target	Low	
EndoProbe®	6.28K	6.19K	6.09K	15
OMA	4.82K	4.75K	4.67K	14
SLA (GL)	3.89K	3.83K	3.81K	13
SLA (SL/SLx)	3.06K	3.01K	2.96K	12
DioPexy Probe	2.53K	2.49K	2.45K	11
G-Probe	1.72K	1.69K	1.66K	9
LIO (GL)	675	665	655	5
LIO (SL/SLx)	521	511	500	4
LIO (LS)	364	357	349	3
ML LIO+	242	220	198	2

Menu #6: Indicates the voltages in the power supply. The +5 V DC value appears in the DURATION window; the +12V DC appears in the REPEAT INTERVAL window. The values you measure should be within ± 0.10V of these values.

Menu #7: Indicates the software version of the unit and appears on the Alphanumeric display located on the left side of the OcuLight front panel. Pressing the Treat/Standby button will display the total number of laser pulses on the system, as described in the Menu Display section.

Menu #8: Go to this menu to enable or disable SmartKey. Press Treat/Standby to make your selection.

Exiting Diagnostics

To exit diagnostics, push the Mode button once. This will place the unit in Standby mode.

2.3 User Preferences:

User Preferences mode allows you to adjust certain parameters that will make the laser system more compatible with individual Doctors preferences. This mode will allow the users to control when the aiming beam will appear, what language the display readout is in, when the auxiliary output is active and provides a review of the 25 alpha numeric messages that can be displayed in the message window.

To enter User Preference mode press the mode button in for approximately five seconds. The message "User Preferences" will appear. To get to the menu of choices press the mode button once. Cycle through the User Preference options using the Treat/Standby button. To change a User Preference option press the Treat/Standby button. If no button is depressed in this mode for a period of approximately one-minute, the laser will automatically return itself to user mode. To manually return to user mode press the mode button.

The following is a description of the User Preference options:

A. Aiming laser on/off in standby

The OcuLight aiming beam can be programmed to either be on when the laser is only in the Treat mode or when the laser is in both Treat and Standby modes. This can be adjusted by cycling through the options until the message "Aiming Laser On or Off Standby" appears in the message window. Pressing the Counter Reset button can now set the preferred aiming laser will appear. Units leaving IRIDEX are programmed with the aiming beam appearing only in Treat mode.

B. Aiming laser on/off with pulse

The OcuLight aiming beam can be programmed to either be on or off when the laser is emitting the treatment beam. This can be adjusted by cycling through the options until the message "Aiming Laser On or Off w/Pulse" appears in the message window. Pressing the Counter Reset button can now set when the aiming laser will appear.

C. Language

The OcuLight has the ability to communicate through the message window in 8 languages. Cycling through the options until the message "Language-" appears can choose the preferred language. The language can now be selected by pressing the Counter Reset button until the desired language appears. The languages that are available are:

1. English
2. Español
3. Francâis
4. Deutsche
5. Italiano
6. Greek
7. Dutch
8. Portuguese

D. MESSAGE REVIEW

The OcuLight will allow you to review all of the messages that may be displayed in the message window. Cycling through the options until "Message Review" appears in the message window can do this. All of the messages will now appear one at a time by pressing the Counter Reset button. Depending on the software version of the OcuLight laser, you may not have all messages detailed here. Available messages are:

1. No Remote Interlock
2. Connect Footswitch
3. Connect SmartKey
4. Self Test
5. Connect Fiber
6. Footswitch Stuck
7. Calibration Required
8. Emergency Stop!
9. Turn Key Off Then On
10. SmartKey Needed
11. SmartKey Not Needed
12. Green Safety Filter?
13. Press Mode to Continue
14. EndoProbe
15. LIO+
16. Slitlamp
17. Spot Size?
18. G-Probe
19. DioPexy
20. Other
21. Call Service Error %d
22. Low Power Actual %d
23. MicroPulse
24. User Preferences
25. Normal Pulse

2.4 CONTROL DESCRIPTIONS

Each of the OcuLight's software states enables and disables various controls function. Some controls, (for example, the FootSwitch), perform differently depending upon which state is active. The following list describes the possible states of the unit and their corresponding controls.

State	Controls
Off	Key Switch
Diagnostics/Initialization	No controls active. Display cycles for 3 seconds and control passes to "Standby" or "Call Service" mode.
Standby	All displays and all controls but FootSwitch is inactive.
Treat	Same controls, as "Standby" but FootSwitch is active.
No SmartKey	Power control inactive, unit displays zeros.
No Fiber	Standby/Treat button and FootSwitch is inactive; other controls are active.
Deliver Pulses	FootSwitch and Standby/Treat controls are active; other controls are disabled.
Low Power	Display flashes actual power that was delivered. Only power level and Standby/Treat controls are active.
Diagnostics	All control except Standby/Treat button is active. Interval and repeat displays show diagnostics data.
Call Service	Call service display is illuminated and error number is shown. No controls are active.

Note that the following modes are always active unless indicated:

Standby/Treat switch: software
Key switch: hardware
Remote interlock: hardware
SmartKey: software/hardware

2.5 Standard Periodic Power Check

Monitoring OcuLight Performance

Copy this page for recording data.

The OcuLight performance should be monitored quarterly using the Diagnostic mode. The following directions describe how to check the unit's performance. Note that there are spaces where information should be entered on a quarterly basis.

1) In diagnostic mode, note that "0" is displayed in the counter window. Press the counter reset button and rotate the Repeat Interval knob one click clockwise to display a "1" in this window.
2) Attach any available IRIDEX delivery device (EndoProbe®, Laser Indirect Ophthalmoscope, Slit Lamp Adapter, etc.). Record the delivery device used.

Type of delivery device used: _____

3) If a Slit Lamp Adapter is used, enter the spot size.

Slit Lamp Adapter spot size: _____

4) Turn the power to 1000 mW. Make sure the delivery device is pointed in a safe direction and fire one shot on the laser. Record the readings in the spaces provided below.

_____

5) Rotate the Repeat Interval knob one click clockwise to display a "2" in the counter window. Record the readings below.

_____

6) Rotate the Repeat Interval knob until a "7" is displayed in the counter window, and then press the Treat button. Record the shot count readings below.

_____

7) Turn the unit off and report these readings to the IRIDEX service department

3.0 Slit Lamp Adapter (SLA) Installation

3.1 Haag-Streit Slit Lamp Adapter (SLAh)

Warning! When changing delivery systems, be sure to place the protective cap on the fiber input. Debris collected on the input face degrades transmission and can lead to a permanently damaged fiber.

Prior to SLA installation insert the Haag-Streit focus post and turn the slit lamp illumination on. Adjust the viewing oculars so that the focus post is crisp and clear. You will not adjust the oculars again during this procedure. Remove focus post.

1) The slit lamp must be properly positioned prior to installing SLAh: Move the Slit lamp as far away from the patient headrest as possible, center it laterally and lock it in position with the thumbscrew located at lower right of slit lamp base. Swing the illumination tower 60-90° clockwise. The tower must be in the normal, full-upright position to install SLAh.

2) Remove IRIDEX SLAh from carry/storage case. Flip Eye Safety Filter Plate down from its latched storage position so that it is free to pivot. If this step is not performed the eye safety filter will collide with the tonometer post potentially cracking the glass.

3) Slide SLAh onto tonometer post. When SLAh is completely bottomed out on post, secure with Locking Thumbscrew at left side of SLAh mounting plate. Rotate the fine focus adjustment knob clockwise, towards the patient, to avoid interference with the prism (They will not interfere when properly aligned for use). Slowly swing illumination tower back into operating position, verifying SLAh clearance.

4) Secure fiber optic cable to patient chin rest in gentle arc (6" minimum bend diameter with Velcro Strap provided. Avoid sharp bends and kinks!).

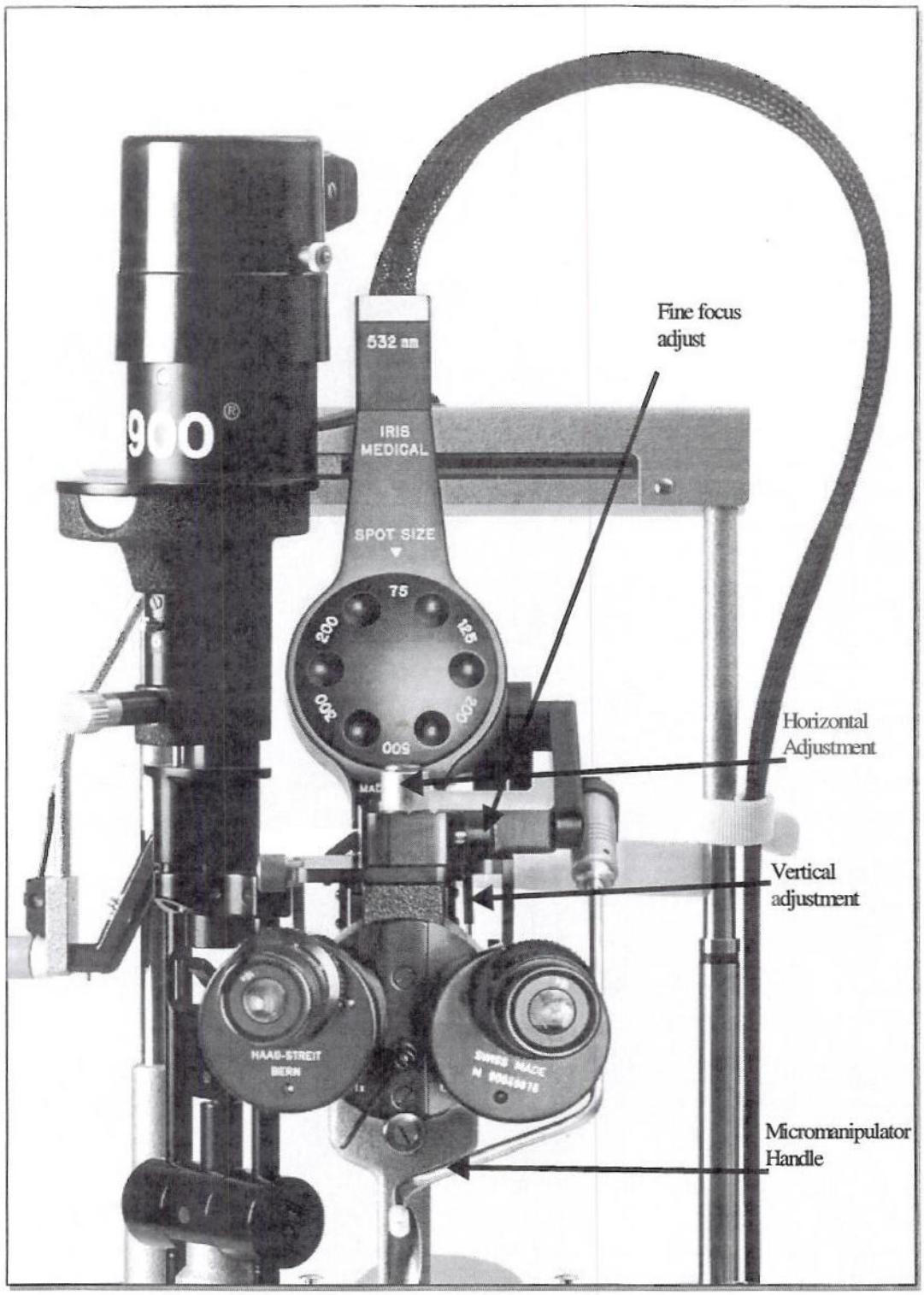
5) Connect fiber and SmartKey to OcuLight laser console.

6) Set up a target (business card, paper, etc.) approximately where the patient's head will be positioned. Move the slit lamp to a position where the white light is in focus. If you have done steps 1-5 correctly you should be able to close the slit to approximately a 1 mm width and swing the illumination tower back and forth with little movement of the slit.

7) Turn the laser on, set the SLA to a 75µm spot size and press Treat in order to view the aiming beam. In this position you should be able to use the fine focus adjustment on the right side of the SLA to bring the aiming beam in focus.

8) Adjust lateral position of laser spot within field of view with Lateral Adjust Lever centered on SLAh mounting plate. Range of adjustment is plus and minus 2.5 mm from centerline of focus post. Orientation of lever can be reset in the field at any time to suit individual preference using slotted flat head screw at top of lever and screwdriver provided with slit lamp.

9) Adjust vertical position of laser spot within field of view with either Vertical Adjust Post on sides of laser mirror frame. Range of adjustment is preset at the factory to plus and minus 2.5 mm from viewing axis. This can be reset in the field to suit individual preferences by adjusting one or both setscrews installed in one side of the mirror support.


532 nm
IRIS
MEDICAL
SPOT SIZE
75
125
200
300
500
Fine focus
adjust
Horizontal
Adjustment
Vertical
adjustment
Micromanipulator
Handle

3.2 Zeiss Slit Lamp Adapter (SLAZ)

Warning! When changing delivery systems, be sure to place the protective cap on the fiber input. Debris collected on the input face degrades transmission.

The slit lamp must be properly positioned prior to installing the SLAZ: Move the Slit Lamp as far away from the patient headrest as possible, center it laterally and lock it in position with the thumbscrew located at lower right of slit lamp base. Swing the illumination tower 60-90° clockwise. The tower must be in the normal, full-upright position to install the SLAZ.

1) Remove the SLAZ from its carrying case.
2) Insert the two pins on the mounting base of the SLAZ into the locating holes on the top of the slit lamp's optical head.
3) Securely tighten the captive thumbscrew on the SLAZ.
4) Rotate the fine focus adjustment knob clockwise, towards the patient, to avoid interference with the prism (They will not interfere when properly aligned for use). Slowly swing illumination tower back into operating position, verifying SLAZ clearance.
5) Remove the dust cap from the input end of the SLAZ optical fiber and insert it into the fiber port on the front of the OcuLight console.
6) Insert the SLAZ electrical cable into the SmartKey connector on the front of the OcuLight console.

The slit lamp is now ready for use.

3.3 Other Types of Slit Lamp Adapters

Please refer to the OcuLight SL/SLx Operator manual or call Technical service.

4.0 SLIT LAMP ADAPTER (SLA)

4.1 Checking the Fiber Input

One of the most delicate parts of any IRIDEX fiber optic delivery device is the fiber face located at the tip of the SMA connector. Located here is a highly polished fiber optic tip that, without proper care, may be irreversibly damaged, leading to costly repair. Since the fiber optic is located on top of a protrusion, it is extremely important to keep this area protected when not in use. A plastic cap is provided for this purpose.

Symptoms of fiber face damage include a measurable loss of output power from 20% to as much as 70%. In most cases, mishandling of the fiber cable without the protective cap installed, or by fingerprints smudged across the fiber face causes the damage. An odd-shaped or low intensity-aiming beam may also be an indication of a damaged fiber.

When a damaged fiber is suspected, a microscope with 150X or 200X magnification is needed. Inspect the top of the fiber ferrule and compare what is seen with Appendix B.2. If there is dirt or debris present, a cotton swab saturated in optical grade methanol may be used to clean the surface. Gently clean the fiber face using a circular motion. If a cleaning is attempted, it is important to try and achieve the picture of a "Good" fiber. If the fiber looks like it is chipped around the edges, the power loss, if any, may be minor, and the fiber may be successfully used. If burns or fractures are present, the fiber will need to be replaced.

Once again, it is extremely important to try and prevent these occurrences by always installing the fiber protection cap when not in use.

4.2 Changing the Fiber

1) Cut the tie wrap at laser console end of the outer sheath.
2) Using a 5/64 hex driver, remove the two #2-56 x 1/2 screws on the strain relief cap.
3) Note how the black outer sheath fits over the flared neck of the strain relief body, and then slide the sheathing back.
4) Using a 5/64 hex driver, remove the two #2-56 x 1/2 screws on the strain relief body.
5) Slide the strain relief body back and the fiber optic cable attached to the fiber optic connector will be exposed.
6) Unscrew the fiber optic connector counter clockwise from the fiber optic adapter.
7) Go to the opposite end of the fiber optic and pull it through the black outer sheath.
8) Take the new fiber optic and feed the small end (leave the red cap on) through the black outer sheath, then insert it through the strain relief cap and the strain relief body.
9) Remove the red cap and screw the fiber optic connector on to the fiber optic adapter until tight.
10) Connect fiber to OcuLight and insert SmartKey.
11) Check the aiming beam against a white card for a circular spot at 75µm setting. Rotate fiber output for a round evenly colored spot.
12) Replace the strain relief body and insert the two screws and tighten.
13) Place the black outer sheath over the flared neck of the strain relief body (as observed in Step 3).
14) Replace the strain relief cap, insert the two screws, and tighten.
15) Go to the opposite end of the fiber optic (the end that screws into the laser) and make sure that it is fairly even with the SmartKey cable).
16) Replace the tie wrap around the black outer sheath.

4.3 Standard Preventive Maintenance

A. MAINTENANCE

The SLA is an extremely reliable laser delivery system; however, like any optical device, it should be handled with care. Observe the following guidelines:

- Do not bend the optical fiber in loops shorter than 8"; instead, loosely drape or coil it on a flat surface.
- Keep the fiber away from areas where it may accidentally be stepped on.
- Keep the fiber input capped when not in use.
- Keep the laser delivery mirror and eye safety filter windows free of fingerprints and dirt.

B. CLEANING

1) Wipe housing surface with a soft cloth dampened with mild detergent.
2) Clean the laser delivery mirror and eye safety filter windows as follows:
   - Wrap a tissue lens (Kodak or equivalent) around one end of a cotton-tipped swab.
   - Place several drops of optical grade methanol or acetone on the tissue.
   - Wipe the lens gently with a swab to remove all dust and debris.
   - If the surface is still not clean, put a clean lens tissue around the end of the swab and gently wipe again.

4.4 Troubleshooting

Problem: SLA will not fit on tonometer post.	
Possible Cause	Solution
Post may be dirty or scratched.	This is a tight tolerance fit. Any dirt or debris may not allow the SLA to fully seat. Inspect and clean carefully.
Tonometer post is slightly large.	Replace with another tonometer post.

Problem: Binocular viewing optics of slit lamp does not focus at focus point.	
Possible Cause	Solution
Eyepieces out of focus.	Adjust the diopter of each eyepiece with the opposite eye closed until focused.
Eyepieces not fully inserted in the binocular tube.	Push eyepieces in.

****Note:** Verify that both magnifications give a sharp view of the focus post simultaneously and the 1 x 8 mm slit is in focus with the focus post.

Problem: Laser spots do not focus on focus post.	
Possible Cause	Solution
Laser focus knob on SLA not adjusted correctly.	Set spot size to smallest available and view the aiming/pilot laser spot on the focus post and adjust the laser fine focus knob to minimum laser spot size.

Problem: No tissue reaction.	
Possible Cause	Solution
Laser and/or SLA malfunction.	Set OcuLight for 100mW and 100msec., select 200µm spot size and focus on black ink of business card. Ink should melt or show a reaction, not ignite.** If not try another delivery device to determine if it is the device or the OcuLight that has the problem.
Power setting too low.	Doctor may be apprehensive about using somewhat higher laser powers than those used in traditional argon laser cases. Refer to treatment guidelines sheet available from IRIDEX.

****Note:** If business card has blue ink it will have a melting threshold about three times higher than black ink.

Problem: OcuLight reads "Connect Fiber."	
Possible Cause	Solution
Fiber input connector not tight.	Tighten until "snug". Do not over-tighten.
Set screw on fiber connector loose.	Using a .035 hex driver, tighten until "snug". Do not over-tighten or you may break chip resistor.

Warning! Always keep the red protective cap attached to the end of the fiber

5.0 LASER INDIRECT OPHTHALMOSCOPE PLUS (LIO+)

5.1 Checking the Fiber Input

One of the most delicate parts of any IRIDEX fiber optic delivery device is the fiber face located at the tip of the SMA connector. Located here is a highly polished fiber optic tip that, without proper care, may be irreversibly damaged, leading to costly repair. Since the fiber optic is located on top of a protrusion, it is extremely important to keep this area protected when not in use. A plastic cap is provided for this purpose.

Symptoms of fiber face damage include a measurable loss of output power from 20% to as much as 70%. In most cases, mishandling of the fiber cable without the protective cap installed, or by fingerprints smudged across the fiber face causes the damage. An odd-shaped or low intensity-aiming beam may also be an indication of a damaged fiber.

When a damaged fiber is suspected, a microscope with 150X or 200X magnification is needed. Inspect the top of the fiber ferrule and compare what is seen with Appendix B.2. If there is dirt or debris present, a cotton swab saturated in optical grade methanol may be used to clean the surface. Gently clean the fiber face using a circular motion. If a cleaning is attempted, it is important to try and achieve the picture of a "Good" fiber. If the fiber looks like it is chipped around the edges, the power loss, if any, may be minor, and the fiber may be successfully used. If burns or fractures are present, the fiber will need to be replaced.

Once again, it is extremely important to try and prevent these occurrences by always installing the fiber protection cap when not in use.

5.2 Changing the Fiber

To replace the Laser Indirect Ophthalmoscope Fiber Optic Cable Assembly, follow the procedure below. This will require use of a .050-inch hex Allen driver.

1) Locate and remove the illumination cable from the lamp housing, as if changing the bulb.
2) Locate and loosen the (2) 0-80 socket head cap screws found in the access holes in the top of the connector protector.
3) Loosen the silver fiber optic connector by turning counter clockwise. This may require pliers, as the connector is held in place with screw locking liquid. (DO NOT LOOSEN THE KNURLED JAM NUT ON THE LENS BARREL)
4) Remove the fiber optic/illumination cable assembly.
5) Replace with the new assembly. Place the connector protector, with the screw holes in the proper orientation, over the end of the fiber optic cable.
6) Install and tighten the fiber optic cable. Enough locking material is left on the connector to prevent loosening. Tighten in place with light pressure from pliers.
7) Slide the connector protector into place and install the 0-80 screws.
8) Connect the illumination cable. Verify proper operation on an OcuLight.

5.3 Standard Preventive Maintenance

A. Maintenance

The LIO+ is an extremely reliable laser delivery system; however, like any optical device, it should be handled with care. Observe the following guidelines:

- Do not bend the optical fiber in loops shorter than 8"; instead, loosely drape or coil it on a flat surface.
- Keep the fiber away from areas where it may accidentally be stepped on.
- Keep the fiber input capped when not in use.
- Keep the dust window and the aspheric lens free of fingerprints and dirt. Clean these surfaces as described below.

B. Cleaning

1) Wipe the headpiece surfaces with a soft cloth dampened with mild detergent.
2) Follow the manufacturer's instructions for using and cleaning the aspheric lens.
3) Several times a year, inspect the binocular eyepieces and clean them by wiping them gently with lens tissue moistened with a lens cleaner.
4) Clean the dust window as follows:
   - Wrap a tissue lens (Kodak or equivalent) around one end of a cotton-tipped swab.
   - Place several drops of 100% ethanol, 100% methanol, or high-grade acetone on the tissue.
   - Wipe the lens gently with a swab to remove all dust and debris.
   - If the surface is still not clean, put a clean lens tissue around the end of the swab and gently wipe it again.

5.4 Troubleshooting

If your LIO+ is not operating properly, the following troubleshooting guide will help you to locate and correct the malfunction:

Problem: No illumination light	
Possible cause	Solution
The illumination spot size and filter selector levers are between detents.	Ophthalmoscope illumination housing is warm, but no light is visible. Reset levers to proper detent.
The illumination cable is not connected to the console or auxiliary power supply	Connect cable as described in the Operator Manual.
The illumination box (Only on pre-1992 models) is not plugged in and/or its switch is not turned on.	Plug the illumination box power cord into the wall socket, turn the unit on, and set the illumination brightness control knob to the intermediate position
The illumination knob on the front console is turned off..	Turn the knob up to full intensity
The illumination lamp (bulb) does not work.	Replace the lamp. Be careful not to touch the glass portion of the bulb as it may inhibit lifetime.

Problem: The aiming beam is large or out focus.
Adjust the distance from the LIO's headpiece to the examination lens. The aiming beam should be sharply defined. The focus is 14.5 inches (36.8cm) from the back of the oculars to the focus point.

Problem: Treatment lesions are variable or intermittent.	
Possible Cause	Solution
The LIO is slightly out of focus, which decreases power density.	Readjust your working distance.
A poorly centered laser beam is clipping on the examination lens or on the patient's iris.	Adjust the laser vertical adjustment knob on the LIO to center the aiming beam in the white light field.
The laser treatment parameters are too close to the tissue-response threshold for consistent uptake.	Increase laser power and/or exposure duration.

Problem: There is no aiming beam or treatment beam.	
Possible cause	Solution
The beam is not centered in the white light field.	Adjust the vertical adjustment knob by turning the adjustment knob to center the beam in the white light Field.
The viewing assembly has shifted forward slightly.	Hold tower assembly and push the viewing assembly into place.
The fiber is broken.	Contact IRIDEX Technical service or your local distributor.

Problem: The OcuLight reads "Connect Fiber."	
Possible Cause	Solution
Fiber input connector not tight.	Tighten until "snug". Do not over-tighten.
Set screw on fiber connector loose.	Using a .035 hex driver, tighten until "snug". Do not over-tighten or you may break chip resistor.

6.0 OPERATING MICROSCOPE ADAPTER (OMA)

6.1 Checking the Fiber Input

One of the most delicate parts of any IRIDEX fiber optic delivery device is the fiber face located at the tip of the SMA connector. Located here is a highly polished fiber optic tip that, without proper care, may be irreversibly damaged, leading to costly repair. Since the fiber optic is located on top of a protrusion, it is extremely important to keep this area protected when not in use. A plastic cap is provided for this purpose.

Symptoms of fiber face damage include a measurable loss of output power from 20% to as much as 70%. In most cases, mishandling of the fiber cable without the protective cap installed, or by fingerprints smudged across the fiber face causes the damage. An odd-shaped or low intensity-aiming beam may also be an indication of a damaged fiber.

When a damaged fiber is suspected, a microscope with 150X or 200X magnification is needed. Inspect the top of the fiber ferrule and compare what is seen with Appendix B.2. If there is dirt or debris present, a cotton swab saturated in optical grade methanol may be used to clean the surface. Gently clean the fiber face using a circular motion. If a cleaning is attempted, it is important to try and achieve the picture of a "Good" fiber. If the fiber looks like it is chipped around the edges, the power loss, if any, may be minor, and the fiber may be successfully used. If burns or fractures are present, the fiber will need to be replaced.

Once again, it is extremely important to try and prevent these occurrences by always installing the fiber protection cap when not in use.

6.2 Changing the Fiber

1) Cut the tie wrap at laser console end of the outer sheath.
2) Using a 5/64 hex driver, remove the two #2-56 x ½ screws on the strain relief cap.
3) Note how the black outer sheath fits over the flared neck of the strain relief body, and then slide the sheathing back.
4) Using a 5/64 hex driver, remove the two #2/56 x ½ screws on the strain relief body.
5) Slide the strain relief body back and the fiber optic cable attached to the fiber optic connector will be exposed.
6) Unscrew the fiber optic connector counter clockwise from the fiber optic adapter.
7) Go to the opposite end of the fiber optic and pull it through the black outer sheath.
8) Take the new fiber optic and feed the small end (leave the red cap on) through the black outer sheath, then insert it through the strain relief cap and the strain relief body.
9) Remove the red cap and screw the fiber optic connector on to the fiber optic adapter until tight.
10) Connect fiber to OcuLight and insert SmartKey.
11) Check the aim beam against a white card for a circular spot at 75µm setting. Rotate fiber output for best spot.
12) Replace the strain relief body and insert the two screws and tighten.
13) Place the black outer sheath over the flared neck of the strain relief body (as observed in Step 3).
14) Replace the strain relief cap, insert the two screws, and tighten.
15) Go to the opposite end of the fiber optic (the end that screws into the laser) and make sure that it is fairly even with the SmartKey cable).
16) Replace the tie wrap around the black outer sheath
17) Always keep the red protective cap on the end of the optic when not in use.

6.3 Standard Preventive Maintenance

A. MAINTENANCE

The OMA is an extremely reliable laser delivery system; however, like any optical device, it should be handled with care. Observe the following guidelines:

- Do not bend the optical fiber in loops shorter than 8 inches; instead, loosely drape or coil it on a flat surface.
- Keep the fiber away from areas where it may accidentally be stepped on.
- Keep the fiber input capped when not in use.
- Keep the micromanipulator mirror and eye safety filter windows free of fingerprints.

B. CLEANING

1) Wipe housing surfaces with a soft cloth dampened with mild detergent.
2) Clean the micromanipulator mirror and eye safety filter windows as follows.

- Wrap a tissue lens (Kodak or equivalent) around one end of a cotton-tipped swab.
- Place several drops of 100% ethanol, 100% methanol, or high-grade acetone on the tissue.
- Wipe the lens gently with a swab to remove all dust and debris.
- If the surface is still not clean, put a clean lens tissue around the end of the swab and gently wipe it again.

6.4 Troubleshooting

Problem: OMA will not fit on the operating Microscope plate.	
Possible Cause	Solution
Plate may be dirty or scratched.	Clean inspect carefully.
Locking screw may be in too far.	Back out locking screw and re-install OMA

** NOTE: A close fit is necessary for accurate location.

Problem: Laser and viewing systems are not parfocal.	
Possible cause	Solution
Correct Microscope objective not installed.	Install only 175mm microscope objective.

Problem: View is blocked or partially blocked by the OMA	
Possible Cause	Solution
Magnification is set less than 10X	OMA is designed for unobstructed view at 10X or greater. See installation instructions if an adjustment is required.
OMA location is not correct	Slide OMA until interference disappears from view.

Problem: OcuLight reads "Connect Fiber".	
Possible Cause	Solution
Fiber input connector not tight.	Tighten until "snug". Do not over tighten.
Set screw on fiber connector loose.	Using a .035 hex driver, tighten until "snug". Do not over-tighten or you may break chip resistor.

7.0 Handling Delivery Devices

7.1 EndoProbe

Note: Only use IRIDEX EndoProbe with OcuLight SLx Lasers

A. Maintenance

The IRIDEX EndoProbe is sold as a single-use disposable item. Discard it after use.

B. Cleaning During Treatment

If the EndoProbe fiber face becomes dirty during treatment, suspend treatment and clean the fiber face as follows:

1) Wrap a lens tissue (Kodak or equivalent) around one end of a cotton-tipped swab.
2) Place several drops of high-grade ethanol, methanol, or propanol on the tissue.
3) Wipe the fiber face gently with the swab to remove all dust and debris.
4) If the surface is still not clean put a clean lens tissue around the end of the swab and gently wipe again.
5) If dirt or discoloration can't be removed from the fiber face with gentle cleaning, then discard the EndoProbe.

C. Probe Protection Requirements

Avoid striking probe ends against hard surfaces.
Coil the fiber optic cable no tighter than 6 inches (15 cm) in diameter.

7.2. G-PROBE

A. Maintenance

The IRIDEX G-Probe is sold as a single-use disposable item. Discard it after use.

B. Cleaning During Treatment

If the G-Probe fiber face becomes dirty during treatment, suspend treatment and clean the fiber face as follows.

1) Wrap a lens tissue (Kodak or equivalent) around one end of a cotton-tipped swab.
2) Place several drops of 100% ethanol, 100% methanol, or 100% propanol on the tissue.
3) Wipe the fiber face gently with the swab to remove all dust and debris.
4) If the surface is still not clean put a clean lens tissue around the end of the swab and gently wipe again.
5) If dirt or discoloration cannot be removed from the fiber face with gentle cleaning, then discard the G-Probe.

7.3 DioPexy

A. Maintenance

The IRIDEX DioPexy Probe is a durable laser delivery device designed for multiple use. As with any optical device, it should be handled with care. The following should be observed: Do not bend the optical fiber into loops with less than 6 inches (15cm) diameter. Instead, loosely drape or coil on a flat surface. Keep the fiber away from aisles where it may be easily be stepped on. Keep the prism free of fingerprints and debris, avoid bending the prism shaft, and avoid striking probe ends against hard surfaces.

B. Cleaning

The DioPexy probe tip must be kept clean to avoid thermal damage at site of application. Wipe probe surfaces with a soft cloth dampened with alcohol and clean the output prism as follows:

1) Wrap a lens tissue (Kodak or equivalent) around one end of a cotton-tipped swab (Q-Tip).
2) Place several drops of 100% ethanol, 100% methanol or 100% propanol on the tissue.
3) Wipe the prism gently with the swab to remove all dust and debris.
4) If the surface is still not clean, put a clean lens tissue around the end of the swab and gently wipe again.

C. DioPexy Protection Requirements

1) Wipe clean with methanol or propanol following instructions described above.
2) Place the protective blue cap over the input port of the fiber optic.
3) Avoid striking probe ends against hard surfaces.
4) Coil the fiber optic cable no tighter than 6 inches (15cm) in diameter.
5) Place in protective custom sterilization tray provided.

D. Sterilization

The IRIDEX DioPexy probe is shipped from the factory non-sterile, but double bagged with a chemical EtO indicator inside the inner bag (NAmSA®EG-60). This chemical EtO indicator will change color from violet to green after exposure to EtO gas.

ETO Gas

When sterilization is required, use only EtO gas. The DioPexy probe can be sterilized at temperatures up to 140° F (60° C) with a relative humidity between 30-60% depending upon the capacity of the EtO sterilization equipment used.

Prior to sterilization follow the cleaning and probe protection instructions described above.

Follow standard industry practice in performing EtO sterilization, which includes placing a chemical EtO indicator strip inside the pouch with the DioPexy probe, and placing one biological spore indicator with each load. Validate DioPexy probe sterility by observing an appropriate color change on the chemical EtO indicator strip inside the pouch and by a negative biological spore test for the load. Do not autoclave or soak.

Sterrad System

The STERRAD system is a low temperature sterilization method using proprietary equipment and processes manufactured by the Advanced Sterilization Products, a division of Johnson & Johnson Medical, Inc.

Parameters used to validate the affectivity of the STERRAD sterilization of the DioPexy Probe using STERRAD include:

- Vacuum Phase: Evacuation of sterilization chamber to 300 mTorr (5-20 minutes).
- Injection Phase: Automatic injection of 1.8 ml of aqueous solution of H_2O_2 and vaporization (6 minutes).
- Diffusion Phase: Diffusion of H_2O_2 in sterilization chamber throughout load (44 minutes).
- Plasma Phase: Low temperature gas plasma with 400 W power at 500mTorr pressure (15 minutes).
- Vent Phase: Return sterilization chamber to atmospheric pressure (5 minutes).
- Total Cycle Time: Approximately 75 minutes.

8.0 DELIVERY DEVICE MAINTENANCE

8.1 OcuLight Delivery Systems

The most expensive part of any IRIDEX delivery device (laser indirect Ophthalmoscope, Slit Lamp Adapter, or any other reusable delivery system) is the polished tip of the fiber optic, located at the end of the device that is inserted into the laser console. The face of the fiber is optically polished to allow maximum transmission of laser light into the fiber optic. All delivery devices are supplied with protective caps to guard against damage that may occur when the device is not in use. It is extremely important to immediately replace these caps when the unit is disconnected from the laser port. The slightest amount of dust, finger oils, or tip damage may reduce laser transmission through the fiber. At first, this may result in only about a 10% drop in output power, but as defects propagate from laser absorption, the delivery device may become greatly compromised. Replacing the protective cap after each use is essential to ensure long life and consistent throughput of your delivery device.

8.2 General Safety

Refer to your OcuLight SL/SLx Operator Manual.

8.3 Laser Safety in the Neonatal Unit

The portability of the OcuLight laser system allows treatment of a baby with stage 3+ Retinopathy of Prematurity (ROP) without transport out of the neonatal intensive care unit (NICU), thereby reducing stress to the infant.

With the advent of the portable diode laser, laser safety in areas that normally do not require laser procedures (such as a NICU), do not have laser safety guidelines in place. This has caused some concern about eye safety of attending personnel as well as other infants in the vicinity of the one being treated.

The ideal safety situation for this type of application would be to completely isolate the infant in an enclosed area, where only attending personnel wearing safety glasses approved for use with the OcuLight are allowed to enter. (The doctor does not need safety glasses because the IRIDEX laser indirect Ophthalmoscope has safety filters built into the viewing assembly.)

Another alternative is the use of portable shields or curtains that can "box in" the infant, doctor, and support personnel while the laser is being used. A fire retardant curtain or shield is adequate. When used only with the OcuLight, the curtains need not be expensive, heavy duty, laser-rated curtains, because of the OcuLight low peak power. The focus point of the OcuLight Laser Indirect Ophthalmoscope is about 14.5 inches when the beam diameter is approximately 1200 microns. At 40 inches away from the laser exit mirror, the beam diameter is already one inch in diameter; therefore, the potential for burning the curtain with a stray laser is very remote and would require extremely long duration and purposeful intent. All personnel inside the enclosure should be wearing approved laser safety glasses designed for the OcuLight.

If curtains or shields are not possible, blankets may be placed over the exposed side of the incubator to protect the infants. All attending personnel in the room must be wearing approved OcuLight safety glasses marked for use at 810 nm. As in any use of a medical laser, the doctors must exercise the most caution because they control the laser emission and direction. Through their safety awareness and experience with the equipment, the laser shields will never have to be tested.

9.0 PACKAGING, SHIPPING, AND HANDLING

9.1 Packaging and Shipping the OcuLight and Accessories

If your IRIDEX laser system or any of its accessories need to be returned to IRIDEX for any reason, it is important that they be properly packaged, preferably in their original shipping containers. Since the laser is small and lightweight, improper packaging may cause additional damage when in transit, which, if severe enough, could lead to a very expensive repair. The following steps should be taken to ensure safe delivery of the unit to IRIDEX:

1) Contact an Iridex technical support representative. Phone (650) 962-8100 or fax (650) 962-0486 to explain why the unit is being returned. Please have the serial number of the device available and the date that you need the unit returned. Obtain a return merchandise authorization (RMA) number.

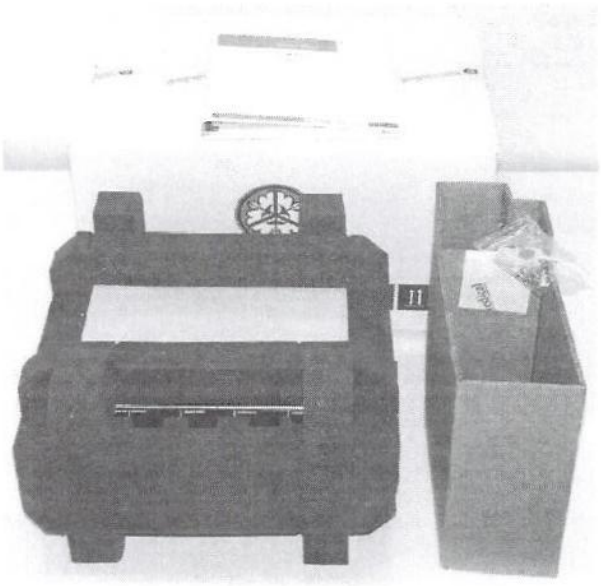
2) Use the original shipping containers. If the original containers are unavailable, contact IRIDEX and replacement-shipping parts will be sent. You will be billed for these materials at our cost and for the shipping charges.

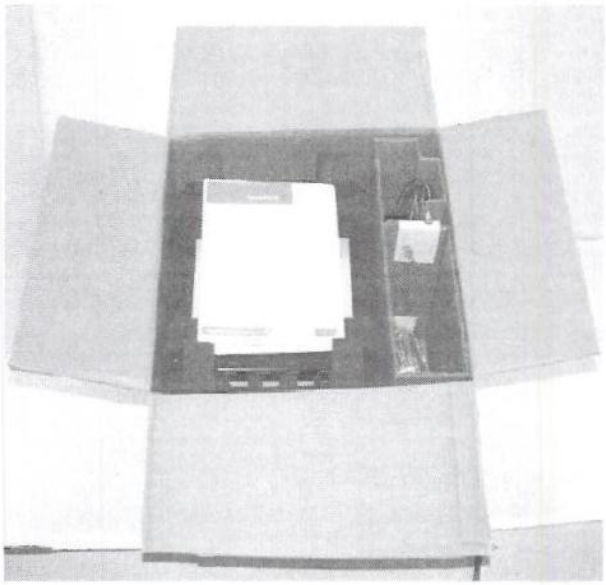
3) Remove all accessories from the laser console. Remove ON/OFF keys, remote interlock plugs, FootSwitch plugs, power cords, and SmartKey. These parts are not needed by our service personnel and if left installed during shipment, may get broken.

4) Package the equipment in the same way that it was originally received. If there are any questions about how to package the equipment, call IRIDEX for instructions.

Warning! Improper packaged equipment is not covered under warranty. If unsure of how to pack the unit, contact IRIDEX for instructions. This may prevent costly repairs

Repackaging for shipment

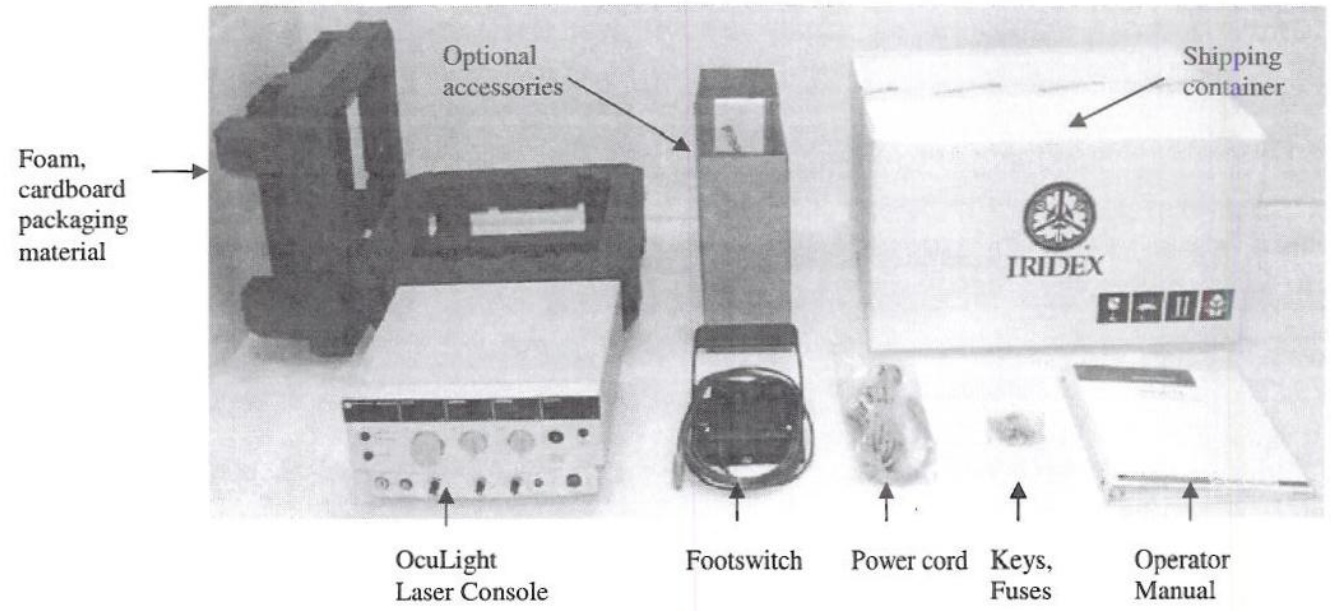




9.2 Packing List

The shipping container (cardboard box) should contain these items:

1) Operator Manual
2) IRIDEX OcuLight Laser Console
3) Detachable Power Cord
4) Keys (2)* with IRIDEX Logo Key Rings
5) FootSwitch Assembly with 5-meter Cable
6) Spare Fuses (2)
7) Packaging foam
8) Other optional accessories (i.e. safety filter, safety eyewear)



10.0 SCHEMATICS

The OcuLight schematics are for the specific use of IRIDEX service personnel who have received formal service training. It is a company policy not to distribute schematics outside of the IRIDEX organization and possession of the OcuLight schematics does not authorize repair or modification or adjustments made by non-authorized personnel. Please contact IRIDEX technical support for further information.

11.0 APPENDICES

APPENDIX A

A.1 Power Measurement & Fiber Equipment Recommendations

A. EXTERNAL POWER METERS

The OcuLight displays the laser power that is being delivered through the currently installed delivery device; however, an external power meter can also measure OcuLight power independently. The following commercially available meters may be used with appropriate calibration factors to measure OcuLight laser power:

- Ophir, 200 Corporate Pl. #7, Peabody, MA 01960
  Model: 10A with compatible display or Orion TH, AN / 2 or Nova or equivalent
  www.ophiroptronics.com
- Coherent, 2303 Lindbergh Street, Auburn, CA 95602
  Model: Laser Mate with 3 W or10 W thermal sensor head or equivalent
  www.coherentinc.com

B. MEASURING LASER POWER

The following pages describe how to externally measure these IRIDEX devices:

- Console/EndoProbe
- Laser Indirect Ophthalmoscope (LIO)
- Slit Lamp Adapter (SLA)

Warning! Wear appropriate eye protection when externally measuring system power.

C. FIBER INSPECTION EQUIPMENT

A video fiber inspection system has been found to be cost effective yet provide enough detail to accurately diagnose and repair fibers for IRIDEX delivery devices. The following company manufactures commercially available product.

P/N 800-G1281K9	Video Fiber Viewer 10X
P/N 800-G992	SMA Adapter

Prior Scientific
80 Reservoir Park Dr.
Rockland, MA 02370-1062
Tel: 781-878-8442

Prior Scientific Ltd.
Unit 4, Wilbraham Rd.
Fulbourn, Cambridge ENGLAND CB1 5ET
Tel. 01223 881711

APPENDIX A.2

Power Measurement - EndoProbe

To measure the console/EndoProbe power:

1. Connect a new IRIDEX EndoProbe to the laser port. Prepare the laser and enter Treat mode. Direct the output end into a properly calibrated, external power meter. Use the aiming beam to verify that the beam is centered and that the spot size is about half the diameter of the active sensor area.

2. Set the duration to 2000 to 5000 milliseconds (2 to 5 seconds) and allow time for the meter reading to settle.

3. Set the OcuLight power to each of the levels listed below, depress the FootSwitch and record the corresponding external power meter readings (in milliwatts).

Displayed power	External power reading	Minimum acceptable	Maximum acceptable
200	_____	160	240
500	_____	400	600
1000	_____	800	1200
2000 (SLx only)	_____	1600	2400

Date: _____

Calibration Checked by: _____

Unit S/N: _____

4. If readings fall outside the minimum/maximum levels listed above, recheck the test setup (power meter, aiming, and EndoProbe.) If a second EndoProbe test also indicates a deviation from the ranges listed above, call IRIDEX or your local representative to arrange for a system adjustment.

5. Place a signed copy of this record in this manual or with your device records.

APPENDIX A.3

Power Measurement - Laser Indirect Ophthalmoscope Plus (LIO+)

To measure the LIO+ power:

1. Connect the LIO+ to the laser port. Direct the output into a properly calibrated, external power meter. Use the aiming beam to verify that the beam is centered and that the spot size is about half the diameter of the active sensor area.

2. Set the duration to 2000 to 5000 milliseconds (2 to 5 seconds) and allow time for the meter reading to settle.

3. Set the OcuLight power to each of the levels listed below, depress the footswitch, and record the corresponding external power meter readings (in milliwatts).

Displayed power	External power reading	Minimum acceptable	Maximum acceptable
200	_____	160	240
500	_____	400	600
1000	_____	800	1200
2000 (SLx only)	_____	1600	2400

Date: _____

Calibration checked by: _____

Unit S/N: _____

4. If reading fall outside the minimum/maximum levels listed above, recheck the test setup (power meter, aiming, and LIO). Check for complete seating of the optical jumper cable and look for any tight bends or cable stress. If the system has not successfully passed the measurement test, the system needs to be adjusted. Call IRIDEX or your local representative to arrange for a system adjustment.

5. Place a signed copy of this record in this manual or with your device records.

APPENDIX A.4

Power Measurement - Slit Lamp Adapter (SLA)

To measure the SLA power:

1. Connect the slit lamp adapter (SLA) to the laser port. Direct the output into a properly calibrated, external power meter. Use the aiming beam to verify that the beam is centered and that the spot size is about half the diameter of the active sensor area.

2. Set the duration to 2000 to 5000 milliseconds (2 to 5 seconds) and allow time for the meter reading to settle.

3. For spot size adjustments of 200, 300, and 500 microns, set the power to the levels listed below, depress the FootSwitch, and record the corresponding external power meter readings (in milliwatts).

Displayed power	External power reading	Minimum acceptable	Maximum acceptable
200	_____	160	240
500	_____	400	600
1000	_____	800	1200
1500 (SL only)	_____	1200	1800
2000 (SLx only)	_____	1600	2400

Date: _____

Calibration checked by: _____

Unit S/N: _____

4. If reading fall outside the minimum/maximum levels listed above, recheck the test setup (power meter, aiming, and SLA). Check for complete seating of the optical jumper cable and look for any tight bends or cable stress. If the system has not successfully passed the measurement test, the system needs to be adjusted. Call IRIDEX or your local representative to arrange for a system adjustment.

5. Place a signed copy of this record in this manual or with your device records.

APPENDIX A.5

Power Measurement - G-Probe

Unlike other OcuLight accessories, the G-Probe power cannot be measured accurately in air because the hemisphere tip on the end of the fiber is designed to be index-matched in fluid.

To measure the G-Probe power:

1. Obtain a small glass petri dish with just enough water to submerge the tip of he G-Probe.
2. Place the measuring head of the power meter on a flat surface with the opening facing up.
3. Place the petri dish with the water on top of he power meter head.
4. Connect the G-Probe to the laser port.
5. Insert the tip of the G-Probe into the water over the opening of the power meter. Note that as the G-Probe tip comes into contact with the water, the aiming beam will collimate dramatically.
6. With the aiming beam centered on the power meter, set the power to the levels listed below, depress the FootSwitch, and record the corresponding external power meter readings.

Displayed power	External power reading	Minimum acceptable	Maximum acceptable
500	_____	400	600
750	_____	600	900
1000	_____	800	1200
1500	_____	1200	1800
2000	_____	1600	2400

Date: _____

Calibration checked by: _____

Unit S/N: _____

7. The measured power should be within ± 20% of the requested power. If he system has not successfully passed the measurement test, the system needs to be adjusted. Call IRIDEX or your local representative to arrange for a system adjustment.
8. Place a signed copy of this record in this manual or with your device records.

APPENDIX A.6

Power Measurement - DioPexy Probe

Copy this page for recording data.

To measure the DioPexy power.

1. Connect the DioPexy to the laser port. Direct the output into a properly calibrated, external power meter. Use the aiming beam to verify that the beam is centered and that the spot size is about half the diameter of the active sensor area.

2. Set the duration to 2000 to 5000 milliseconds (2 to 5 seconds) and allow time for the meter reading to settle.

3. Set the power to the levels listed below, depress the FootSwitch, and record the corresponding external meter readings (in milliwatts).

Displayed power	External power reading	Minimum acceptable	Maximum acceptable
500	_____	400	600
750	_____	600	900
1000	_____	800	1200
1500	_____	1200	1800

Date: _____

Calibration Checked By: _____

Unit S/N: _____

4. If readings fall outside the minimum/maximum levels listed above, recheck the test setup (power meter, aiming, and DioPexy). Check for complete seating of the optical jumper cable and look for any tight bends or cable stress. If the system has not successfully passed the measurement test, the system needs to be adjusted. Call IRIDEX or your local representative to arrange for a system adjustment.

5. Place a signed copy of this record in this manual or with your device records.

B.1 Error Code Chart

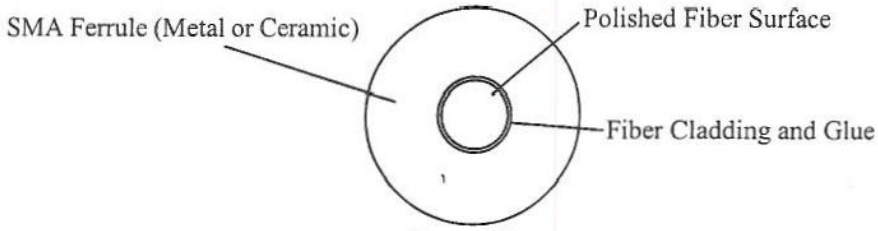
When the OcuLight detects an internal failure, it will shut off the laser, disable all controls, and the message: "Call Service" will be illuminated along with an error code number indicating which failure was detected. To verify that a problem has occurred, switch the key off and back on. If the failure is still displayed, turn the unit off and contact the IRIDEX service department. A list of error codes and corresponding descriptions appear below.

Error Code	Description
1	Reset error. The microprocessor has detected an unexpected system reset.
2	Power supply error. The power supply voltage is out of range.
3	DAC ADC Error. The power supply voltage is out of range.
4	Data memory error. The microprocessor has detected a RAM failure.
5	Light too low error. The light measured from one of the two photocells is below the level requested.
6	Light too high error. The light measured from one of the two photocells is above the requested level.
7	Software error. The microprocessor has detected an error in the program.
8	ROM Checksum Error. The check sum in the EPROM did not verify.
9	RAM Checksum Error. The RAM has lost its battery-backup, calibration values.
10	Timer error. The internal timer used for pulse width measurement has failed.
11	Watchdog error. The watchdog timer failed to reset the CPU within the specified time.
12	RC Constant Error. The system clock and the real time clock timing reference do not match.
13	Connector Error. The connector from the photocells may be loose.
14	Light loop error. Light was measure from one of the photocells when the laser should have been off.
15	Photocell mismatch error. The two photocells are reading different values for the laser power.
16	Laser ON/OFF switch error. The laser power supply primary control is inoperative.
17	Footswitch error. The footswitch circuit or footswitch wiring is experiencing problems.
18	Interlock error. The remote interlock may not be connected. System power was cycled too fast for the timing circuits. The operator has pushed the "emergency stop button" during initialization of the unit.
19	Laser Supply Low Error. The control to the laser is out of range.
20	Laser Supply High Error. The control to the laser is out of range.
21	Laser AMP Error. The current sense amplifier is in error.
22	Shunt High Error. The bias circuit for the laser is out of range.
23	Shunt Low Error. The bias circuit for the laser is out of range.
24	DAC Timer Error. The DAC timer ranges are improper.
99	NMI Error. The non-maskable interrupt has an error.

B.2 Fiber Inspection Chart

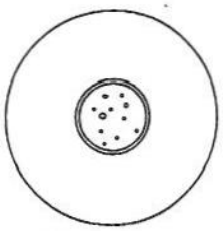
Fiber Inspection Chart

Viewed at 150-200X Magnification



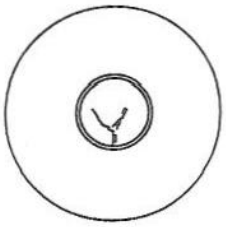
Good Fiber

Center light gray portion is smooth and even in coloration with no visible particles or defects



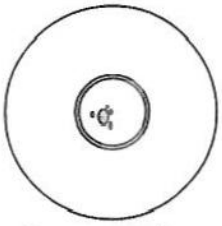
Dirty Fiber

Center light gray portion has dark particles on surface. Power output could be 70-90% of requested power. May be cleaned with optical grade acetone or methanol.



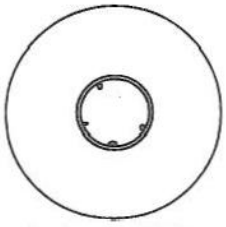
Fractured Fiber

Center light gray portion has dark fracture on surface. Power output could be 30-70% of requested power. Fiber needs to be replaced.



Burned Fiber

Center light gray portion has dark pits or craters on surface. Power output could be 30-80% of requested power. Sometimes can be repolished if crater is shallow, if not, the fiber needs to be replaced.



Chipped Fiber

Center light gray portion has dark pits or craters on surface edges. Chips may extend inward towards center of fiber and may not affect the output power. Power output could be 60-100% of requested power. Fiber should be replaced if power is less than 80% of requested power